

The NGAL Test™ Reagent Kit

| REF/Cat. No. | ST001CA | | ST002CA | ST003CA |
|--------------|----------------------------|----------|--------------------------------|----------------------------|
| Prod. name | The NGAL Test™ Reagent Kit | | The NGAL Test™ Calibrator Kit | The NGAL Test™ Control Kit |
| | R1 | R2 | 50, 150, 600, 1500, 3000 ng/mL | Low and High |
| | 1 x 35 mL | 1 x 7 mL | 5 x 1 mL | 3 x 1 mL x 2 levels |

Number of determinations: 1 mL of immunoparticle suspension **R2** provides 25 cuvette readings with the provided settings in this application. The dead volume of the analyzer and reagent container should be added when calculating the required amount of reagent.

PERFORMANCE DATA

The performance data shown were obtained by the manufacturer for this particular analyzer model. For additional performance data and product application, please read the instructions for use accompanying the product carefully. Each individual laboratory should validate the use of The NGAL Test™ on its system.



LIMIT OF DETECTION (LoD)

Not tested on this analyzer model. Refer to Instructions for Use for more information.

RANGE

The measuring range of The NGAL Test™ is 25 - 3000 ng/mL on the Abbott Architect® c8000®.

SECURITY RANGE

The NGAL Test™ was tested for antigen excess with NGAL concentrations up to 40,000 ng/mL: NGAL concentrations above 3000 ng/mL are above the measuring range. concentrations $\geq 12,000$ ng/mL were marked (RAC). The user should consider the requirement for entering prozone check settings.

| Theoretical NGAL level, ng/mL | Measured NGAL concentration, ng/mL | Mark |
|-------------------------------|------------------------------------|------|
| 3000 | 2986 | |
| 4000 | 3330 | |
| 8000 | 4028 | |
| 12,000 | 3967 | RAC |
| 16,000 | 3812 | RAC |
| 20,000 | 3639 | RAC |
| 24,000 | 3409 | RAC |
| 28,000 | 3223 | RAC |
| 32,000 | 3101 | RAC |
| 36,000 | 2858 | RAC |
| 40,000 | 2802 | RAC |

RAC: Reaction Check

LIMIT OF QUANTIFICATION (LoQ)

The LoQ was determined to be 25 ng/mL on this analyzer model. Observed results:

| 25 ng/mL | Mean (ng/mL) | SD | CV % | n |
|----------|--------------|-----|------|----|
| | 18.4 | 2.5 | 13.6 | 20 |

PRECISION

| REF | Mean (ng/mL) | SD | CV % | n |
|--------------|--------------|-----|------|----|
| ST003CA Low | 202.3 | 3.0 | 1.5 | 10 |
| ST003CA High | 490.4 | 7.9 | 1.6 | 10 |

INTERFERENCE

Not tested on this analyzer model. Refer to Instructions for Use for more information.

METHOD COMPARISON

NGAL measurements have been compared to measurements on a Hitachi 917. Data is available on request.

CALIBRATION STABILITY

It is recommended to recalibrate every 4 weeks, when reagent lots change or quality control results fall outside the range as established by the individual laboratory.

TROUBLE SHOOTING

If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact instrument supplier or reagent supplier.

¹ Architect® and c8000® are registered trademark of Abbott Laboratories, North Chicago, Illinois, USA.

APPLICATION PARAMETERS

General parameters

| | | | |
|----------------|------|---------------------|-------------|
| Name: | NGAL | Assay type: | Photometric |
| Assay number: | *1 | Assay availability: | Enabled |
| Assay version: | 1 | Cal version: | 1 |

Reaction definition

| | | | |
|-----------------------|-----------------|-----------------------------|---------|
| Reaction mode: | End Up | Main read time: | 27 - 28 |
| Primary wavelength: | 572 | | |
| Secondary wavelength: | | Color correction read time: | 0 - 0 |
| Last read required: | 33 | Blank read time: | 19 - 20 |
| Absorbance range: | 0.0000 – 0.0000 | | |
| Sample blank type: | Self blank | | |
| Blank assay: | | | |

Reagent/Sample

| | | | |
|--------------------|--------|------------------------|--------|
| Reagent: | NGAL | R2 reagent volume: | 40 |
| R1 reagent volume: | 120 | R2 water volume: | 0 |
| R1 water volume: | 0 | R2 dispense mode: | Type 0 |
| R1 dispense mode: | Type 0 | Diluent dispense mode: | Type 0 |
| Diluent name: | Saline | | |

| Dilution name | Sample volume | Diluted sample volume | Diluent volume | Water volume | Dilution factor |
|---------------|---------------|-----------------------|----------------|--------------|-----------------|
| Normal | 2.4 | | | | 1:1.00 |
| Rerun 1 | 15.0 | 2.4 | 105.0 | | 1:8.00 |
| Rerun 2 | 6.0 | | | | 1:1.00 |

Validity Checks

| | | | |
|-------------------------------|------------|---------------------|---------|
| Reaction check type: | Rate RATIO | Read time B range: | 19 - 20 |
| Read time A range: | 32 - 33 | Minimum absorbance: | 0.0150 |
| Calculation limit: | 0.18 - 9.9 | Rate linearity %: | 0 |
| Maximum absorbance variation: | | | |

*1 To be defined by operator.

Calibration Parameters

Calibration method: Spline
 Use cal factor from: Factor:
 Full interval hours: 0 Adjustment interval hours: 0
 Adjustment type: None Adjustment level:
 Expected cal factor: 0.00 Default ordering type: Full
 Expected factor tolerance %: 0.0 Blank absorbance range: 0.0000 - 0.0000
 Span: Span absorbance range: 0.00 - 0.00
 Maximum curve fit: 0.00
 Calibrator set name: *1 Replicates: 3

| Cal level | Concentration | Sample volume | Diluted sample | Diluent volume | Water volume |
|-----------|---------------|---------------|----------------|----------------|--------------|
| Blank | 0 | 2.4 | | | |
| Cal. 1 | 50 | 2.4 | | | |
| Cal. 2 | 150 | 2.4 | | | |
| Cal. 3 | 600 | 2.4 | | | |
| Cal. 4 | 1500 | 2.4 | | | |
| Cal. 5 | 3000 | 2.4 | | | |

Smart Wash

| Cal level | Reagent/Assay | Wash | Volume | Replicates | Wash protocol |
|-----------|---------------|------|--------|------------|---------------|
| | | | | | |

Result Parameters

Linearity range: 25 - 3000

Flag range specification:

| Gender | Age | Normal range | Extreme range |
|--------|-----|--------------|---------------|
| | | - | - |

Interpretation Parameters

Result Unit

Result concentration unit: ng/mL Correlation factor: 1.0000
 Result decimal places: 0 Intercept: 0.0000